

1 ENERGY AND ENVIRONMENT CABINET

2 Department for environmental protection

3 Division of Water

4 (Amendment)

5 401 KAR 8:040. Laboratory certification.

6 RELATES TO: KRS 224.10-100, 224.10-110, 40 C.F.R. 141 Subpart C, Appendix A, 141.28,  
7 141.201-211, Appendix A B, EO 2008-507, 2008-531

8 STATUTORY AUTHORITY: KRS 224.10-100~~(28)~~, 224.10-110(2), 42 U.S.C. 300f - 300j-26  
9 ~~[Chapter 6A Subchapter XII]~~, 40 C.F.R. 141.28

10 NECESSITY, FUNCTION, AND CONFORMITY: KRS Chapter 224.10-110(2) authorizes  
11 the ~~[Environmental and Public Protection]~~ cabinet to enforce the ~~[statutes and]~~ administrative  
12 regulations promulgated by the secretary for the regulation and control of the purification of water  
13 for public and semipublic use. EO 2008-507 and 2008-531, effective June 16, 2008, abolish the  
14 Environmental and Public Protection Cabinet and establish the new Energy and Environment  
15 Cabinet. This administrative regulation establishes procedures for certification of commercial or  
16 public water system laboratories to test for various analysis categories or constituents within an  
17 analysis category ~~[contaminant groups or constituents within a contaminant group]~~.

18 Section 1. Laboratory Certification. (1) The U.S. Environmental Protection Agency or the  
19 cabinet shall evaluate a ~~[certify]~~ public water system ~~[systems]~~ or a commercial laboratory that  
20 performs analysis ~~[laboratories performing analyses]~~ for a public water system for certification  
21 ~~[systems]~~.

(2) Contracting by the cabinet with a third party to conduct laboratory evaluations ~~[evaluate laboratories]~~ and make recommendations to the cabinet regarding ~~[for]~~ certification shall be in accordance with the ~~["]~~Manual for the Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality Assurance~~["]~~ and Kentucky Drinking Water Laboratory Certification Program Manual.

(3)(a) ~~[(2)]~~ Certification may be for one (1) or more analysis categories ~~[contaminant groups]~~ or for a single constituent within an analysis category ~~[a contaminant group]~~.

(b) Each analysis category ~~[contaminant group]~~ shall require a different certification, but qualification for different certifications may be evaluated ~~[accomplished]~~ during one (1) inspection.

Section 2. Application. (1) An initial certification request may be made at any point during the calendar year.

(2) A laboratory seeking ~~[Laboratories that apply for]~~ certification shall submit a written request for ~~[the]~~ certification to the cabinet. The request shall include:

(a) A statement of the analysis category ~~[contaminant group]~~ for which certification is requested; ~~[and]~~

(b) A list of the analytic methods for each analyte for which certification is requested; and

(c) ~~[(b)]~~ Payment of the ~~[annual]~~ fee established ~~[specified]~~ in 401 KAR 8:050, Section 2(4) ~~[for the contaminant group]~~ for the ~~[which]~~ certification ~~[is]~~ requested.

(3) ~~[(2)]~~ The cabinet may request other information necessary to determine eligibility ~~[suitability]~~ for certification as described in the ~~["]~~Manual for the Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality Assurance~~["]~~ and Kentucky Drinking Water Laboratory Certification Program Manual.

1       (4) An applicant may request recertification in accordance with 401 KAR 8:050, Section 2.

2       Section 3. [~~Standards. Laboratories shall be certified in accordance with the "Manual for the~~  
3 ~~Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality~~  
4 ~~Assurance", and this administrative regulation.~~

5       ~~Section 4. Performance Evaluations. Performance evaluations shall be performed for~~  
6 ~~laboratories certified or for those laboratories seeking certification, to conduct chemical or~~  
7 ~~bacteriological analyses.~~

8       ~~Section 5. The cabinet shall certify all public water system laboratories or commercial~~  
9 ~~laboratories performing analyses for public water systems. All analyses required by 401 KAR~~  
10 ~~8:010 through 8:700 shall be performed in a certified laboratory and shall be in accordance with 40~~  
11 ~~C.F.R. Part 141 Subpart C, March 12, 2007. Certifications shall be performed on an annual basis~~  
12 ~~with fees payable as set forth in 401 KAR 8:050.~~

13       ~~Section 6.] Public Water System Laboratory [~~Laboratories~~]. (1) A public water system~~  
14 ~~[systems] may establish a laboratory [~~their own laboratories~~]. Each laboratory [~~These laboratories~~]~~  
15 ~~shall be [~~properly~~] certified annually [~~and shall maintain annual certification~~].~~

16       (2) Failure to achieve or maintain annual certification shall not relieve the public water system  
17 of the responsibility to report [~~for reporting~~] results of the required analyses from a certified  
18 laboratory.

19       Section 4. [~~Section 7.] Requirements. Maintenance of certification shall require [~~be dependent~~~~  
20 ~~on] the following [~~factors~~]:~~

21       (1) Analysis. Analysis shall be performed [~~Analyses. A certified laboratory shall perform an~~  
22 ~~analysis for a contaminant group or constituent]~~ in accordance with the appropriate approved  
23 method found in [~~"U.S.~~] 40 C.F.R. Subpart C, including Appendix A, effective June 3, 2008

1 ~~[141.23(k)(1) March 25, 2003, and 141.24(e), October 29, 2002].~~

2 (2) Submission of analysis ~~[Submittal of routine]~~ results. Except as provided in subsection (5)  
3 of this section, the result of analysis ~~[results of analyses]~~ performed in a certified laboratory  
4 ~~[laboratories]~~ by or ~~[and]~~ for a public water system ~~[systems]~~ shall be submitted to the cabinet by  
5 the tenth day of the month following the ~~[specified]~~ testing period for which the analysis was  
6 performed ~~[samples were taken]~~ and shall be submitted to the public water system as soon as  
7 possible. The public water system shall be responsible for this reporting requirement.

8 (3) Performance evaluation sample. A performance evaluation (PE) sample ~~[samples]~~ shall be  
9 analyzed and the results shall be submitted to the cabinet at times specified in the ["]Manual for the  
10 Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality  
11 Assurance["], and Kentucky Drinking Water Laboratory Certification Program Manual not to  
12 exceed twice a year, unless additional results shall be required ~~[are needed]~~ in accordance with the  
13 ["]Manual for the Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures  
14 Quality Assurance["] and Kentucky Drinking Water Laboratory Certification Program Manual.

15 (4) Deviations.

16 (a) ~~[Any]~~ Deviation from accepted practice specified in the ["]Manual for the Certification of  
17 Laboratories Analyzing Drinking Water; Criteria and Procedures Quality Assurance["] and  
18 Kentucky Drinking Water Laboratory Certification Program Manual, listed on a report resulting  
19 from an on-site inspection, shall be corrected.

20 (b) A written explanation of the deviation and action ~~[steps]~~ taken to correct it shall be  
21 submitted to the cabinet within thirty (30) days of the issuance of the inspection report.

22 (5) Violations.

23 (a) A ~~[the]~~ laboratory shall report any violation of a maximum contaminant level ~~[levels]~~ or

1 other violation requiring ~~[of]~~ tier one public notification pursuant to 401 KAR 8:070 to the public  
2 water system and the cabinet within twenty-four (24) hours of sample analysis, in accordance with  
3 40 C.F.R. 141.201-141.211, Appendix A and Appendix B, effective July 1, 2007 ~~[violations, as~~  
4 ~~explained in 401 KAR 8:070, to the public water system and the cabinet within twenty-four (24)~~  
5 ~~hours of sample analysis]~~.

6 (b) A ~~[The]~~ public water system shall begin check sampling within twenty-four (24) hours of  
7 notification of a ~~[the]~~ violation.

8 (6) Emergency provision. Laboratories shall make provisions to receive and test samples  
9 twenty-four (24) hours a day during an emergency ~~[emergencies]~~.

10 Section 5. ~~[Section 8.]~~ Right of Entry. A ~~[The]~~ certified laboratory ~~[lab]~~ shall permit the  
11 cabinet to conduct on-site surveys during normal business hours, without prior notification.

12 Section 6. ~~[Section 9.]~~ Revocation of certification and downgrading of certification shall be in  
13 accordance with the procedures established ~~[set forth]~~ in the ~~["]~~Manual for the Certification of  
14 Laboratories Analyzing Drinking Water; Criteria and Procedures Quality Assurance~~["]~~ and  
15 Kentucky Drinking Water Laboratory Certification Program Manual.

16 (1) A laboratory that has ~~[Laboratories which have]~~ been notified of a change of certification  
17 shall, within seventy-two (72) hours, notify the public water systems that ~~[which]~~ the laboratory  
18 serves of the change in certification status and any impact that change could have on the public  
19 water system.

20 (2) A laboratory ~~[These laboratories]~~ may provide monitoring reports by contracting with a  
21 certified laboratory that shall comply with ~~[follow]~~ the ~~["]~~Manual for the Certification of  
22 Laboratories Analyzing Drinking Water; Criteria and Procedures Quality Assurance~~["]~~ and  
23 Kentucky Drinking Water Laboratory Certification Program Manual.

Section 7. ~~[Section 10.]~~ Recognition of an Out-of-state Laboratory ~~[Laboratories]~~. (1) The cabinet may recognize a laboratory located ~~[laboratories]~~ outside ~~[of]~~ Kentucky upon submission of proof by the laboratory that it is certified by the ~~[of]~~ Environmental Protection Agency certification, or ~~[certification]~~ by a state having primary enforcement responsibility for the provisions of the Safe Drinking Water Act, 42 U.S.C. 300f through 300j-26 ~~[et seq.]~~, or that is ~~[proof that a laboratory has been]~~ certified pursuant to the requirements of the Safe Drinking Water Act, 42 U.S.C. 300f through 300j-26 ~~[et seq.]~~, requirements.

(2) A water system located in Kentucky that has entered ~~[Kentucky water system may enter]~~ into a contract with a certified out-of-state laboratory shall comply with ~~[, if reporting]~~ time intervals and capabilities established ~~[are maintained]~~ in ~~[accordance with]~~ the ~~["]~~Manual for the Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality Assurance~~["]~~ and Kentucky Drinking Water Laboratory Certification Program Manual.

(3) If on-site inspection shall be conducted for certification of an out-of-state laboratory ~~[laboratories]~~, the laboratory ~~[laboratories]~~ shall bear the cost.

Section 8. ~~[Section 11.]~~ Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Manual for the Certification of Laboratories Analyzing Drinking Water; Criteria and Procedures Quality Assurance; Fifth Edition, January 2005", Publication EPA 815-R-05-004; and ~~[, U.S. EPA, Office of Drinking Water, Washington, D.C., is incorporated by reference.~~

~~(2)]~~ (b) "Kentucky Drinking Water Laboratory Certification Program Manual", December 2008.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Division of Water, 200 Fair Oaks Lane ~~[14 Reilly Road]~~, Frankfort, Kentucky,

1 Monday through Friday, 8 a.m. to 4:30 p.m.

401 KAR 8:040 “Laboratory Certification” approved for promulgation:

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Date

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Leonard K. Peters, Secretary  
Energy and Environment Cabinet



**PUBLIC HEARING AND PUBLIC COMMENT PERIOD:** A public hearing on this administrative regulation shall be held on February 25, 2009 at 10:00 A.M. (Eastern Time) at 300 Fair Oaks Lane, Conference Room 301B and 301C, Frankfort, Kentucky. Individuals interested in being heard at this hearing shall notify this agency in writing by February 18, 2009, five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted until March 2, 2009. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

**CONTACT PERSON:** Abigail Powell, Regulations Coordinator  
Division of Water  
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## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 401 KAR 8:040

Contact Person: Sandy Gruzesky, Director

**(1) Provide a brief summary of:**

- (a) What this administrative regulation does:** This administrative regulation provides procedures for the certification of laboratories performing analysis for public and semipublic water systems.
- (b) The necessity of this administrative regulation:** This administrative regulation is necessary to assure that Kentucky has an adequate number of certified laboratories to conduct analysis for public water systems.
- (c) How this administrative regulation conforms to the content of the authorizing statutes:** KRS 224.10-110 authorizes the cabinet to enforce regulations for the purification of drinking water for public and semipublic use. 40 C.F.R. 142.10(3) requires states to have a program for laboratory certification in order to obtain primary enforcement responsibility for the Safe Drinking Water Act.
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:** This administrative regulation allows the cabinet to certify laboratories to carry out necessary analysis of drinking water.

**(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:**

- (a) How the amendment will change this existing administrative regulation:** This administrative regulation is being amended in order to adopt the latest analytical techniques approved by the U. S. Environmental Protection Agency and to adopt a new certification manual developed for Kentucky laboratories.
- (b) The necessity of the amendment to this administrative regulation:** The amendment to this administrative regulation will allow certified laboratories to use the most recently approved analytical techniques. The laboratory certification manual is a supplement to the federal manual to reflect unique needs in Kentucky.
- (c) How the amendment conforms to the content of the authorizing statutes:** KRS 224.10-110 authorizes the cabinet to enforce regulations for the purification of drinking water for public and semipublic use. 40 C.F.R. 142.10(3) requires states to have a program for laboratory certification in order to obtain primary enforcement responsibility for the Safe Drinking Water Act. The amendments to this administrative regulation allow certified laboratories to use the latest approved analytical techniques, and allow the cabinet to tailor its certification procedures to unique circumstances in Kentucky.
- (d) How the amendment will assist in the effective administration of the statutes:** The ability to use the latest approved analytical techniques will allow a public water system and its laboratory to tailor monitoring to achieve the most cost effective means of compliance with monitoring requirements.

**(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:** Currently, there are 43 certified microbiology laboratories and 23 certified chemistry laboratories in Kentucky. Nineteen

microbiology and four chemistry laboratories are municipally owned. Outside Kentucky, there is one certified microbiology laboratory and fifty-two certified chemistry laboratories. These laboratories serve 491 public, 50 semipublic, and 7 bottled water systems in Kentucky.

**(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:**

- (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:** The amendment to this regulation will give a certified laboratory increased flexibility in pursuing techniques or methods to monitor drinking water.
- (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):** The amendments to this administrative regulation will not increase costs.
- (c) As a result of compliance, what benefits will accrue to the entities identified in question (3):** A certified laboratory will have a wider selection of methods for testing drinking water from which to choose. This could reduce costs to public water systems.

**(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:**

- (a) Initially:** No additional cost is anticipated.
- (b) On a continuing basis:** No additional cost is anticipated.

**(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation?** This administrative regulation is funded by a combination of state general funds, fees, and federal funds provided to support the enforcement of the Safe Drinking Water Act.

**(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:** This proposed amendment will not require an increase in laboratory certification fees or an increase in funding.

**(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees:** This proposed amendment does not directly or indirectly establish or increase fees.

**(9) TIERING: Is tiering applied? (Explain why or why not)**

Yes. A laboratory may be certified for a single analysis category, a group of analysis categories, or for all analysis categories that are monitored in drinking water.

## **FISCAL NOTE ON STATE OR LOCAL GOVERNMENT**

Regulation #: 401 KAR 8:040

Contact Person: Sandy Gruzesky, Director

- 1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?**

Yes   X   No       

If yes, complete questions 2-4.

- 2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?**

This administrative regulation applies to certified laboratories that do analysis for contaminants in public and semipublic water systems. Public water systems are often owned by city governments or organized under county governments. Other entities, such as associations, privately-owned or investor-owned entities, may have a water system.

- 3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.**

KRS 224.10-110 authorizes the cabinet to enforce regulations for the purification of drinking water for public and semipublic use. 40 C.F.R. 142.10(3) requires that the cabinet have a laboratory certification program as a condition to having primary enforcement responsibility for the Safe Drinking Water Act.

- 4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.**

**(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?** This administrative regulation will not generate any revenue in the first year.

**(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?** This administrative regulation will not generate any revenue in subsequent years.

**(c) How much will it cost to administer this program for the first year?** No additional costs are anticipated.

**(d) How much will it cost to administer this program for subsequent years?** No additional costs are anticipated.

**Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.**

**Revenues (+/-):**

**Expenditures (+/-):**

**Other Explanation:**

## FEDERAL MANDATE ANALYSIS COMPARISON

Administrative Regulation#: 401 KAR 8:040

Contact Person: Sandy Gruzesky, Director

**1. Federal statute or regulation constituting the federal mandate.**

40 C.F.R. 142.10(3)

**2. State compliance standards.**

KRS 224.10-110 authorizes the Cabinet to enforce regulations for the purification of drinking water for public and semipublic use.

**3. Minimum or uniform standards contained in the federal mandate.**

40 C.F.R. 142.10(3) requires states to have a laboratory certification program as a condition to receiving primary enforcement responsibility for the Safe Drinking Water Act.

**4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements than those required by the federal mandate?**

This regulation provides different requirements from the federal regulation, but they are not more stringent. The different requirements are specific to Kentucky. A state certification manual is being incorporated by reference. This manual clarifies and formalizes the state's administrative certification process. The manual establishes the Kentucky-specific requirements for those laboratories wishing to become certified. The federal regulation recommends an administrative process but does not dictate the state's specific requirements for obtaining certification.

**5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.**

This regulation provides different requirements from the federal regulation, but they are not more stringent. The different requirements are specific to Kentucky. A state certification manual is being incorporated by reference. This manual clarifies and formalizes the state's administrative certification process. The manual establishes the Kentucky-specific requirements for those laboratories wishing to become certified. The federal regulation recommends an administrative process but does not dictate the state's specific requirements on obtaining certification.

**DETAILED SUMMARY OF MATERIAL  
INCORPORATED BY REFERENCE  
IN 401 KAR 8:040**

The following materials are incorporated by reference in 401 KAR 8:040

- I. This administrative regulation incorporates by reference the “Kentucky’s Drinking Water Laboratory Certification Manual for Chemistry and Microbiology Laboratories”, December 2008.

The state certification Manual clarifies and formalizes the state’s administrative certification process. The Manual establishes the Kentucky-specific requirements for a laboratory wishing to be certified. The federal regulation recommends an administrative process but does not dictate a state’s specific requirements for obtaining certification.

This Manual consists of 596 pages.